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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,327	10/03/2005	Akio Inui	480.1001	7240

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

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03/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,327	INUI ET AL.	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4 and 7-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 09 January 2008 has been entered in full. Claims 1-3 and 5-6 have been cancelled and claims 4, and 7-9 have been amended. Claims 10-13 have been added.

Claims 4 and 7-13 are pending and under examination.

Sequence compliance

Applicants' amendments to the specification filed 01/09/2008 have satisfied the requirements of the sequence rules (37 CFR 1.821 – 1.825).

Claim Objections

Applicant's amendments made to claims 4 and 7-9 filed on 01/09/2008 have overcome the objections of claims 4 and 7-9. The objections of claims 4 and 7-9 have been withdrawn.

Rejections maintained

Claim Rejections - 35 USC § 112 (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 7-9 remain rejected, and new claims 10-12 are also rejected, under 35 USC 112, first paragraph, for the reasons already of record on pages 2-4 of the Office Action mailed 07/05/2007.

At page 7 of the response, Applicant argues that the specification provides clear guidelines on how to screen for a ghrelin analog antagonist (See, for example, page 8, lines 21-28).

Applicant's claim amendments have been fully considered but are not found persuasive. The amendments of claims 4 and 7-9 reciting "a ghrelin analog antagonist" do not satisfy the written description requirement because a ghrelin analog antagonist has been broadly interpreted by the Examiner as encompassing any ghrelin analog antagonists.

To provide adequate written description and evidence of possession of claimed genus, the specification must provide efficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure/function correlation, and other identifying characteristics. Accordingly, in the absence of sufficient recitation of distinguishing structural/physical and identifying characteristics, the specification does not provide adequate written description of the claimed genus.

The broad brush discussion of screening analogues of ghrelin antagonist does not constitute a disclosure of a representative number of members. No such analogues were made or shown to have activity. Only the ghrelin analog antagonists [D-Lys-3] -GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P are disclosed. The specification's general discussion of screening for analgues constitutes an invitation to experiment by trial and error. Such does not constitute an adequate written description for the claimed analogues.

In addition, although Applicant discloses the functional activity the polypeptide in the claimed method, Applicant has not provided any structural characteristics for the ghrelin analog

antagonist. While the specification teaches that the GHS-R antagonists, which are used as active ingredients in the present invention, are substances that can bind to GHS-R, thereby inhibiting the effects of the agonists (page 8, lines 13-15) and that ghrelin analogs as designated in the present invention include those which have one or more of the 28 amino acids deleted, substituted or added as long as they have the desired appetite promoting action (page 10, lines 6-9), the claim fails to disclose that the structure of the ghrelin analog antagonist utilized in the claimed method.

Therefore, Applicant has not satisfied the requirement for written description because the claimed ghrelin analog antagonist encompasses a genus of polypeptide whose structure is not described. The specification does not provide any description of the special features, which are critical to function of the genus claimed. Furthermore, the specification does not provide compensatory structural or correlative teachings sufficient to one of skill in the art to isolate and identify the polypeptide encompassed by the claims.

Furthermore, no structural identifying characteristics or properties of the instant ghrelin analog antagonist such that one of skill would be able to predictably identify the encompassed variant biological and chemical entities recited for the ghrelin analog antagonist of the instant claims. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus and the written description requirement is not satisfied.

Claim Rejections - 35 USC § 112 (Enablement)

Claims 4 and 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) a method for reducing food intake comprising administering the GHS-R antagonist [D-lys-3]-GHRP-6 or [D-Arg-1, D-Phe-5, D-Trp-7, 9 Leu-11]

substance P and (2) a method for lowering the blood glucose level comprising administering [D-Lys-3]-GHRP-6, (3) a method for treating diabetes mellitus comprising administering [D-Lys-3]-GHRP-6, and (4) a method for treating obesity comprising administering [D-Lys-3]-GHRP-6, a method of suppressing appetite comprising administering [D-Lys-3]-GHRP-6, does not reasonably provide enablement for (1) a method for lowering the blood glucose level comprising administering a ghrelin analog antagonist (2) a method of preventing diabetes mellitus which comprises administering an effective dose of GHS-R antagonist, wherein said antagonist is selected from the group consisting of a ghrelin analog antagonist, [D-lys-3]-GHRP-6, and [D-Arg-1, D-Phe-5, D-Trp-7, 9 Leu-11] substance P, (3) a method of preventing obesity which comprises administering an effective dose of GHS-R, wherein said antagonist is selected from the group consisting of a ghrelin analog antagonist, [D-lys-3]-GHRP-6, and [D-Arg-1, D-Phe-5, D-Trp-7, 9 Leu-11] substance P. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Claims 4 and 7-9 remain rejected, and new claims 10-12 are also rejected, under 35 USC 112, first paragraph, for the reasons already of record on pages 5-9 of the Office Action mailed 07/05/2007.

At page 7 of the response, Applicant argues that each of said methods comprises administering an effective dose of a GHS-R antagonist selected from the group consisting of a ghrelin analog antagonist, [D-Lys-3] -GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P. In addition, Applicant alleges that the claimed methods using [D-Lys-3] -GHRP-6 and [D-Arg-1, D- Phe-5, D-Trp-7, 9, Leu-11] substance P are described and enabled by the specification, for example, page 23, line 18 to page 25, line 20 and the specification fully

supports the claimed methods using a ghrelin analog antagonist, which are described in detail on page 10, line 6 to page 12, line 6.

Applicant's claim amendments have been fully considered but are not found persuasive. The amendments of claims 4 and 7-9 reciting "a ghrelin analog antagonist" do not satisfy the enablement requirement because Applicant has not provided any identifying characteristics for the ghrelin analog antagonist utilized in the claimed method. The specification does not provide any correlation between the structural features and the functional activities of the ghrelin analog antagonist utilized in the claimed method, so that one skilled in the art would not be able to predict that all possible ghrelin analog antagonists can treat or prevent diabetes mellitus or obesity. For instance, the specification teaches ghrelin analogs as designated in the present invention include those which have one or more of the 28 amino acids deleted, substituted or added as long as they have the desired appetite promoting action (page 10, lines 6-9). Thus it would require undue experimentation to practice the invention commensurate in scope with the claims because the claims are broadly drawn to any ghrelin analog antagonists utilized in the claimed method.

In addition, it would require undue experimentation for one of skill in the art to make/use the claimed method because the term "preventing" has been interpreted by the Examiner as meaning that an activity will not occur 100%, i.e. diabetes mellitus and obesity will not occur. However, the specification does not disclose complete prevention of diabetes mellitus and obesity and undue experimentation would be required of the skilled artisan to determine the quantity of a ghrelin analog antagonist to be administered, the best route of administration, the duration of treatment in order to prevent diabetes mellitus and obesity in a patient.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al. (US 2001/0020012 A1, published September 6, 2001, filed January 29, 2001). The basis of this rejection is set forth for claims 4 and 7-9 at pages 5-10 of the previous Office action of 05 July 2007.

The rejection of claims 4, 7-9, and the newly added claims 10-13 is maintained. Applicant's response and arguments filed on 01/09/2008 have been fully considered but they are not persuasive.

At page 8 of the response, Applicant argues that Andersen does not anticipate claims 4 and 7-9, at least because it does not disclose the claimed GHS-R antagonist. Anderson relates to the use of a ligand for the growth hormone secretagogue receptor type 1A (GHS-R 1 A) for the regulation of food intake. See Andersen, page 1, paragraph [0001]. Andersen, however, does not disclose a GHS-R antagonist selected from the group consisting of a ghrelin analog antagonist, [D- Lys-3] -GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P. Anderson also does not disclose the use of said GHS-R antagonist in lowering blood glucose level; preventing or treating diabetes mellitus; preventing or treating obesity; or suppressing appetite.

Applicant's claim amendments have been fully considered but are not found persuasive. A ghrelin analog antagonist has been broadly interpreted by the Examiner as encompassing any ghrelin analog antagonists including a ligand for the growth hormone secretagogue receptor

type 1A (GHS-R 1 A). The method of administering a ghrelin analog antagonist of the instant application meets the limitations of administering the antagonist for the receptor GHS-R 1A taught by the reference by Andersen et al. (US 2001/0020012 A1, published September 6, 2001, filed January 29, 2001).

In addition, in response to applicant's arguments, the recitation “lowering blood glucose level; preventing or treating diabetes mellitus; preventing or treating obesity; or suppressing appetite” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Andersen et al. teach a method for treatment or prevention of obesity (page 2, paragraph [0012]) Type II diabetes (page 1, paragraph [0013]) with the antagonist for the receptor GHS-R 1A (page 2, paragraph [0022]), which a ghrelin analog antagonist, meeting the limitations of claim 7.

Although the reference is silent upon lowering blood glucose, the administration of a compound for the treatment of diabetes would inherently result in lowering blood glucose level, as required by the claim 4. For example, it is well known in the prior art that diabetes mellitus is associated with continuous and pathologically elevated blood glucose concentration (Chatterrji et al. (US Patent 6,949,261; column 1, lines 48-49).

In addition, Andersen et al. teach a method for treatment of or prevention (page 2, paragraph [0012]) of obesity (page 1, paragraph [0011]) with the antagonist for the receptor GHS-R 1A (page 2, paragraph [0022]), meeting the limitations of claim 8.

Furthermore, Andersen et al. teach a method for treatment of or prevention (page 2, paragraph [0022]) for regulation of food intake with the antagonist for the receptor GHS-R 1A (page 6, claims 6 and 8) meeting the limitations of claim 9.

In addition, Andersen et al. teach that the GHS-R antagonist is administered centrally or intracisternally, and peripherally or parenterally (page 3, paragraph [0042]) meeting the limitations of claims 10-13.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
March 7, 2008

/Robert Landsman/
Primary Examiner, Art Unit 1647